# In the United States Court of Federal Claims
**OFFICE OF SPECIAL MASTERS**
**No. 21-1194V**

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| JAMIE HANDLEY,<br><br>Petitioner,<br>v.<br><br>SECRETARY OF HEALTH AND HUMAN SERVICES,<br><br>Respondent. | Chief Special Master Corcoran<br><br>Filed: February 21, 2024 |

*Andrew Donald Downing, Downing, Allison & Jorgenson, Phoenix, AZ , for Petitioner.*

*Austin Joel Egan, U.S. Department of Justice, Washington, DC, for Respondent.*

## FACT RULING DISMISSING TABLE CLAIM[1]

On April 13, 2021, Jamie Handley filed a Petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*[2] (the "Vaccine Act"), alleging that she suffered a shoulder injury related to vaccine administration ("SIRVA") as a result of a tetanus-diphtheria-acellular pertussis ("Tdap") vaccination administered to her on June 30, 2020. Pet. at 1, ECF No. 1. The case was assigned to the Special Processing Unit of the Office of Special Masters.

For the reasons discussed below, I find it more likely than not that Petitioner's injury was not limited to the shoulder in which the vaccine was administered, and that another condition or abnormality is present that could explain Petitioner's alleged injury.

[1] Because this Ruling contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

Petitioner's Table claim is therefore **DISMISSED** (although the matter may remain viable as a causation-in-fact claim).

## I. Relevant Procedural History

Petitioner submitted an affidavit along with her Petition, plus medical records, a vaccine consent form, VAERS report, and a statement of completion filed on August 23, 2021. ECF Nos. 1, 6-14. On June 18, 2022, Petitioner filed an Amended Petition. ECF No. 22. Approximately five months later, while this case awaited medical review, Petitioner submitted a settlement demand to Respondent on November 16, 2022. ECF No. 30. On November 17-18, 2022, Petitioner filed additional medical records. ECF Nos. 31-32.

Because Respondent had not completed a medical review of the case within a year of activation to SPU, Petitioner was permitted to file a Motion for a Ruling on the Record. Petitioner did so on February 21, 2023. Petitioner's Motion, ECF No. 35. Approximately two months later, on April 10, 2023, Respondent filed a status report stating that he has determined that this case is not appropriate for compensation and requesting to file a Rule 4(c) report. ECF No. 36. Respondent filed his Rule 4(c) report and Response to Petitioner's Motion for a Ruling on the Record on May 25, 2023. Respondent's Response, ECF No. 37. Petitioner filed her Reply on May 31, 2023. Petitioner's Reply, ECF No. 38. This matter is now ripe for consideration.

## II. Relevant Factual Evidence

Petitioner's medical history reveals several reports of falls resulting in injuries to both shoulders and her back. For example, roughly two years prior to the subject Tdap vaccination, on August 31, 2018, Petitioner fell from a ladder and reported left shoulder, back, and left leg/hip pain. Ex. 4 at 310. The physical examination showed "tenderness in both shoulders[,] especially the left posterior aspect." *Id.* at 313. Petitioner also reported bilateral shoulder pain through October 23, 2018.[3] *Id.* at 631. Additionally, approximately three months before the subject Tdap vaccination, in March 2020, Petitioner experienced another fall and subsequently reported right shoulder and hip pain the following month (in April 2020). *Id.* at 132, 137. Petitioner experienced ongoing right shoulder issues allegedly associated with this fall. *See,* e.g., Ex. 1 ¶ 10.

On June 30, 2020, following an injury to her foot (requiring sutures), Petitioner (then 71 years old) received the subject Tdap vaccination vaccine in her left deltoid. Ex.

[3] During this visit, Petitioner reported that she had not fallen during the past year. Ex. 4 at 637. This is inconsistent with her previous reports of a fall in August 2018. *Compare* Ex. 4 at 310, *with* Ex. 4 at 637.

5 at 15. In her affidavit, signed on March 30, 2021, Petitioner noted that "[h]ours passed" after receiving the subject vaccination and "the arm got worse. It swelled up, got hot and it was starting to get more difficult to lift [her] arm." Ex. 1 ¶ 7. Petitioner has further attested that the day following her vaccination, she called the urgent care where she received it. Ex. 1 ¶ 8. According to Petitioner, "they said just give it a few days and [they would] see [her] back to get the foot checked out." *Id.* The medical records from this facility do not contain a record of this conversation. *See generally,* Ex. 5.

Petitioner's follow up visit with the urgent care facility (for her foot wound) was ten days later, on July 10, 2020. Ex. 5 at 17. Petitioner's foot wound was infected, and she was prescribed antibiotics. *Id.* at 19-20. The records do not reflect any report of left shoulder pain at this time. *See id.* However, Petitioner attests that during this visit, she "talked [with the doctor] about the pain in [her] arm and shoulder, [and] he mentioned that it could be because of the administration of the shot as it happens sometimes." Ex. 1 ¶ 8.

On July 15, 2020, Petitioner had a telehealth visit with her primary care provider ("PCP"). Ex. 4 at 110. Petitioner's presenting problems were listed as her foot injury, a "question of a reaction to a tetanus vaccination including neck discomfort [and] mid back pain," hypertension, chronic back pain, and coronary artery disease ("CAD"). *Id.* at 107. Her chief complaint was "severe left arm and foot pain." *Id.* Petitioner's PCP did not provide diagnoses related to Petitioner's purported left arm/shoulder pain. *See id.* at 110.

Petitioner had a follow-up with the urgent care facility for the removal of her foot sutures on July 17, 2020. Ex. 5 at 21. The records do not reflect a complaint of left shoulder pain. *See id.* at 21-24.

On July 27, 2020, Petitioner had a telehealth visit with her PCP for "medication refills." Ex. 4 at 102. The record lists Petitioner's presenting problems as, in relevant part, a "reaction to tetanus vaccination with arm pain [and] generalized muscle aches and pains," and chronic low back pain. *Id.* During the review of systems, however, Petitioner reported only lumbar spinal pain. *Id.* at 105. Interestingly, despite this being a telehealth visit, the physical examination revealed "tenderness on palpation [and] joint tenderness," but did not specify the location. *Id.* The diagnoses did not include one related to left shoulder pain. *See id.* However, Petitioner was prescribed a "trial of Medrol Dosepak to possibly offset the systemic symptoms of the tetanus vaccination adverse reaction." *Id.*

At a telehealth follow-up visit with her PCP on August 5, 2020, Petitioner reported that "her aches and pains from the adverse reactions with the tetanus shot improved" following the Medrol Dosepak. Ex. 4 at 101. The musculoskeletal review of systems notes

"no joint pain, back pain. Normal gait and [range of motion ("ROM")] to all extremities." *Id.* No diagnoses were made related to Petitioner's left shoulder. *See id.*

Petitioner had two additional telehealth visits with her PCP for other ailments in August 2020, including one on August 12, 2020, and another on August 27, 2020. Ex. 4 at 89-96. Petitioner did not mention left arm/shoulder pain or her Tdap vaccination at either of these telehealth visits. *See id.*

Petitioner next saw her PCP in-person on September 24, 2020. Ex. 4 at 84. Her presenting problems included left shoulder pain. *Id.* Upon examination, Petitioner exhibited "tenderness to palpation over the anterior aspect of the left shoulder." *Id.* at 87. Petitioner's diagnoses included left shoulder pain, and she received a steroid injection in her left shoulder. *Id.* Petitioner did not attribute her left shoulder pain to the Tdap vaccination at this time. *See id.*

On September 30, 2020, Petitioner presented to her PCP for "a follow-up. She states that she had a reaction from her tetanus shot, and woke up from the pain the night after she got her immunization. She had pain for two days after the injection." Ex. 4 at 79. The presenting problems was listed, in part, as "improving [sic] in the left shoulder pain now *right* shoulder pain." *Id.* (emphasis added). Petitioner's musculoskeletal examination was normal with "normal movement of all extremities, no joint tenderness or muscle tenderness." *Id.* at 82. Petitioner was diagnosed with right shoulder pain, and she received a steroid injection in the right shoulder. *Id.*

Approximately one month later, on October 27, 2020, Petitioner followed up with her PCP for issues, including bilateral shoulder pain and chronic back pain. Ex. 4 at 74. Her physical examination was normal except for "paralumbar spinal tenderness to palpation." *Id.* at 77. Petitioner's diagnoses included right shoulder pain and she was prescribed a Medrol Dosepak for "bilateral shoulder pain." *Id.* at 77-78.

Petitioner had an annual wellness visit with her PCP on November 9, 2020. Ex. 4 at 68. Petitioner's presenting problems included right shoulder pain but did not mention left shoulder issues. *Id.* Upon examination, Petitioner exhibited "[n]ormal movement of all extremities, no joint tenderness or muscle tenderness." *Id.* at 71. Petitioner's diagnoses included acute pain of the right shoulder and Petitioner received a second steroid shot in her right shoulder. *Id.* at 72-73.

Petitioner saw her PCP at least three additional times over the next three months but did not report left shoulder (or right shoulder) pain or limitations at any visit during this

time. *See,* e.g., Ex. 4 at 58-61 (a November 12, 2020 visit); Ex. 4 at 54-57 (a November 23, 2020 visit); Ex. 4 at 49-53 (a December 21, 2020 visit).

On February 1, 2021, Petitioner had a follow-up with her PCP. Ex. 4 at 44. The presenting problems list included "right shoulder pain secondary to [a] rotator cuff tear." *Id.* Petitioner's review of systems was positive for right shoulder pain, and she had a positive right drop arm test upon examination. *Id.* at 47. Petitioner received a third steroid injection in her right shoulder and her PCP accordingly ordered an MRI of the right shoulder. *Id.* at 48. The left shoulder was not mentioned. *See id.*

During a visit with her PCP one month later, on March 1, 2021, Petitioner reported bilateral shoulder pain. Ex. 4 at 39. An examination revealed "paralumbar spinal tenderness to palpation" and "tenderness over the anterior and posterior aspects of both shoulders." *Id.* at 42. Petitioner was diagnosed with a right rotator cuff tear, and she was referred to orthopedics. *Id.*

Three days later, on March 4, 2021, Petitioner presented for an initial orthopedic consultation. Ex. 8 at 2. Her "chief complaints [we]re pain and stiffness," and she was there "to assess her right shoulder. She's undergone previous treatment for severe glenohumeral osteoarthritis [("OA")] including injections in the past." *Id.* Petitioner attributed her right shoulder pain to a fall in April 2020 and her left shoulder pain to the tetanus shot "9 mo[nths] ago." *Id.* She rated her right shoulder pain at a 9/10 and the left at a 7/10. *Id.* A physical examination revealed pain with elevation of her right shoulder but no such documentation for the left shoulder. *Id.* at 4. Petitioner was diagnosed with primary OA of her right shoulder. *Id.* Petitioner attested that she asked this orthopedist "about SIRVA [but] he didn't know what [she] was talking about." Ex. 1 ¶ 14.

A Vaccine Adverse Event Reporting System ("VAERS") report was completed on March 12, 2021. Ex. 3. The report notes that the "adverse event started" on June 30, 2020 – the day of the subject Tdap vaccination. *Id.* The report states that Petitioner "returned to [the urgent care facility where she received the subject vaccination], saw [the] same doctor [and was] told to give it time." *Id.* The form continues, the "site was swollen, red, and hot. [Petitioner c]ouldn't move or lift arm." *Id.* The form appears to have been completed by Petitioner's PCP. *See id.*

Petitioner returned to her PCP on March 16, 2021. Ex. 4 at 34. The presenting problem included bilateral shoulder pain and "ongoing numbness and pain of the left arm [that] started after a Tdap injection [in] June of last year." *Id.* Petitioner's musculoskeletal examination was normal. *Id.* at 37. Nonetheless, Petitioner's diagnoses included a "vaccine reaction." *Id.* Her PCP noted that Petitioner had "a chronic injury of the left arm

after a Tdap injection" and the plan was to "refer to urgent care visit for details of the initial reaction of the arm." *Id.* Petitioner was also referred to orthopedics for "all ongoing pain of the right shoulder" and another Medrol Dosepak was prescribed. *Id.*

During a visit with her PCP on March 19, 2021, Petitioner's PCP noted that "neurology and orthopedic referrals were recently sent to help coordinate care for [Petitioner's] right shoulder pain." Ex. 4 at 31. The notes continue, "[n]eurology referrals were sent as well to help treat shoulder injury related to vaccine administration (SIRVA), [her] pain has been consistent and [she] has not been able to meet with a specialist who can help her manage the pain." *Id.*

Petitioner sought care with a second orthopedist on March 23, 2021, "for evaluation of her RIGHT shoulder." Ex. 4 at 441 (emphasis in original). She reported that her right shoulder was injured on April 15, 2020, after a fall. *Id.* Petitioner also stated that "she got a tetanus shot last June and her pain has not resolved." *Id.* Upon examination, Petitioner's ROM was more restricted in her right shoulder compared to the left. *Id.* at 443. Petitioner exhibited normal strength in both shoulders. *Id.* The records do not contain additional discussion related to Petitioner's left shoulder during this visit. *See id.*

X-rays of Petitioner's right shoulder were obtained following this visit on March 23, 2021. Ex. 4 at 443. The x-rays showed a glenoid cyst and "bone on bone at [the] glenohumeral joint." *Id.* Petitioner's treating orthopedist reviewed the x-rays and diagnosed her with primary OA of the right shoulder. *Id.* Surgery (shoulder replacement) was discussed as a treatment option but the physician opined that "arthroscopic surgery would be unpredictable at best in this case because of the degree of joint damage." *Id.* at 444.

Petitioner followed up with her PCP on April 1, 2021. Ex. 4 at 16. Petitioner discussed issues with her right shoulder and chronic back pain but did not mention left shoulder complaints. *Id.* at 16-20. Petitioner was prescribed another Medrol Dosepak for her right shoulder pain. *Id.* at 20.

X-rays of Petitioner's left shoulder were discussed during a follow-up visit on April 6, 2021. Ex. 10 at 5. The x-rays revealed "near bone on bone at [the] glenohumeral [joint]" in the left shoulder. *Id.* at 7. Petitioner's physician discussed conservative treatment of the left shoulder, as arthroscopic surgery "would be unpredictable at best . . . because of the degree of joint damage." *Id.*

Approximately four months later, Petitioner followed up with her orthopedist on August 5, 2021, for "RIGHT shoulder degenerative joint disease." Ex. 11 at 59 (emphasis

in original). An examination of Petitioner's right shoulder was performed but the same was not done on the left side. *Id.* at 61.

On August 11, 2021, Petitioner underwent a total arthroplasty of the right shoulder due to end-stage degenerative joint disease. Ex. 11 at 63. Petitioner presented for post-operative follow up care on August 24, 2021, and December 7, 2021. *Id.* at 26-28, 57-58. Petitioner did not discuss her left shoulder during any of these visits. *See id.*

At the time she began post-operative physical therapy ("PT") for her right shoulder on September 2, 2021, Petitioner reportedly "struggle[d] w[ith] bed mobility due to the pain in the [left] shoulder." Ex. 11 at 54. Petitioner received PT treatment for her right shoulder, only. *See id.* at 54-56; *see also id.* at 30-52. However, during a November 22, 2021 PT appointment, Petitioner again complained of continued "difficulty with [her l]eft shoulder that she attributes to her Sirva [sic]." *Id.* at 38. Petitioner was discharged from PT on January 12, 2022, because she did not return following her last visit (on December 7, 2021). *Id.* at 25-26. At the time of discharge, left shoulder pain was noted. *Id.* at 25.

On February 1, 2022, Petitioner returned to her orthopedist reporting improvement in her right shoulder symptoms. Ex. 11 at 21. She also had a "new problem of primary [OA], left shoulder" and "a mass on her anterior LEFT shoulder." *Id.* (emphasis in original). Petitioner reported left shoulder pain "immediately since [her] tetanus shot." *Id.* A physical examination revealed pain in the left impingement arcs and a repeat x-ray showed glenohumeral degenerative joint disease of the left shoulder. *Id.* at 23-24. Petitioner's orthopedist noted a "[t]emporal relationship to injection." *Id.* at 24.

Petitioner underwent an MRI of the left shoulder on February 23, 2022. Ex. 11 at 17-19. The MRI was interpreted to show "bone on bone degenerative joint disease." *Id.* at 17. Petitioner's orthopedist noted that Petitioner's left shoulder primary OA was "[e]nd stage [and was a] chronic problem with exacerbation/progression." *Id.* The orthopedist opined that Petitioner was a "candidate for total shoulder arthroplasty" of the left shoulder. *Id.* Petitioner continued to seek care with her orthopedist for left shoulder pain through at least March 2022. *Id.* at 16.

Approximately seven months later, in October 2022, Petitioner presented to the emergency department for acute right shoulder pain after reaching for an object. Ex. 12 at 11. Upon her return home, Petitioner followed up with her orthopedist on October 11, 2022. Ex. 11 at 7. Her chief complaint during this visit was "left shoulder pain/right shoulder pain" but Petitioner emphasized the acute but ongoing pain in her right shoulder. *Id.* Nonetheless, Petitioner underwent a "repeat clinical evaluation of [her l]eft shoulder degenerative joint disease." *Id.* Petitioner's orthopedist noted that the care of Petitioner's

left shoulder was "[o]n hold while working on the RIGHT" shoulder. *Id.* at 8 (emphasis in original). Indeed, the chief complaint during Petitioner's October 25, 2022 follow-up was listed as "right shoulder pain," only. *Id.* at 4. No other medical records related to Petitioner's left shoulder have been filed.

## III. Authority

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). In addition to requirements concerning the vaccination received, the duration and severity of petitioner's injury, and the lack of other award or settlement,[4] a petitioner must establish that she suffered an injury meeting the Table criteria, in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination she received. Section 11(c)(1)(C).

Section 11(c)(1) also contains requirements concerning the type of vaccination received and where it was administered, the duration or significance of the injury, and the lack of any other award or settlement. *See* Section 11(c)(1)(A), (B), (D), and (E). With regard to duration, a petitioner must establish that he suffered the residual effects or complications of such illness, disability, injury, or condition for more than six months after the administration of the vaccine. Section 11(c)(1)(D).

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of an influenza vaccine. 42 C.F.R. § 100.3(a)(XIV)(B). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests *all* of the following:

> (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
>
> (ii) Pain occurs within the specified time frame;

[4] In summary, a petitioner must establish that she received a vaccine covered by the Program, administered either in the United States and its territories or in another geographical area but qualifying for a limited exception; suffered the residual effects of her injury for more than six months, died from her injury, or underwent a surgical intervention during an inpatient hospitalization; and has not filed a civil suit or collected an award or settlement for her injury. *See* § 11(c)(1)(A)(B)(D)(E).

(iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and

(iv) No other condition or abnormality is present that would explain the patient's symptoms (*e.g.* NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10).

A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, the Federal Circuit has recently "reject[ed] as incorrect the presumption that medical records are always accurate and complete as to all of the patient's physical conditions." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021). Medical professionals may not "accurately record everything" that they observe or may "record only a fraction of all that occurs." *Id.*

Medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery v. Sec'y of Health & Hum. Servs.*, 42 Fed. Cl. 381 at 391 (1998) (citing *Blutstein v. Sec'y of Health & Hum. Servs*., No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Hum. Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." Section 13(b)(2). "Such a finding may

be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table." *Id*.

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe Sec'y of Health & Hum. Servs*., 110 Fed. Cl. 184, 204 (2013) (citing § 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Hum. Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

## IV. Respondent's Objections and Findings of Fact

### A. Factual Findings Regarding QAI Criteria for Table SIRVA

After a review of the entire record, I find that a preponderance of the evidence demonstrates that Petitioner has failed to establish more than one QAI requirement for a Table SIRVA. As a result, her Table claim cannot succeed.

#### 1. Prior Condition

The first QAI requirement for a Table SIRVA is lack of a history revealing problems associated with the affected shoulder which were experienced prior to vaccination and would explain the symptoms experienced after vaccination. 42 C.F.R. § 100.3(c)(10)(i).

Respondent disputes that Petitioner meets the first requirement under the QAI for a Table SIRVA. Specifically, Respondent notes that Petitioner "had a prior history of intermittent bilateral shoulder pain prior to her Tdap vaccination, which may [] explain her alleged symptoms." Respondent's Response at 13 (citing Ex. 4 at 310, 631).

The filed records in this case are not wholly consistent with Respondent's contention. For example, the medical records from August 31, 2018, show that Petitioner experienced left shoulder pain at that time, but attributed such pain to a fall. Ex. 4 at 310. Yet in October 2018, Petitioner reported experiencing bilateral shoulder pain, but a possible explanation for such ongoing pain was not provided. *See id.* at 631. Further, on March 4, 2021, during Petitioner's initial orthopedic evaluation for her alleged vaccine-related injury, Petitioner stated that "she's undergone previous treatment for severe glenohumeral [OA] including injections in the past." Ex. 8 at 2.

Despite these notations, the medical records do not appear to contain treatment for said left or bilateral shoulder pain past her initial treatment for her fall in August 2018. *See generally,* Ex. 4; *see also* Ex. 4 at 313 (an August 31, 2018 note prescribing steroids for Petitioner's shoulder pain); Ex. 4 at 305 (a note from September 5, 2018, showing that Petitioner was "feeling better after the steroids."). It is therefore unlikely this left shoulder pain contributed to Petitioner's post-vaccination symptoms.

However, Petitioner's statement made during her March 4, 2021 orthopedic visit (that she has received treatment for her OA in the past), is not only vague, but the diagnosis does not seem to be corroborated by the submitted medical records from Petitioner's treatment prior to this visit. It is not clear when Petitioner received this diagnosis, who provided the diagnosis, in which arm the diagnosis was made, or how this alleged diagnosis could be connected to her later diagnosis of the same condition.

Accordingly, based on the current record, I am unable to glean whether Petitioner experienced a condition pre-vaccination that would explain her post-vaccination symptoms. I therefore cannot find that this QAI element *alone* is a basis for dismissal of the Table claim.

**2. Onset of Pain**

A petitioner alleging a SIRVA claim must also show that she experienced the first symptom or onset within 48 hours of vaccination (42 C.F.R. § 100.3(a)(XIV)(B)), and that her pain began within that same 48-hour period (42 C.F.R. § 100.3(c)(10)(ii) (QAI criteria)). Respondent argues that "[t]he only evidence that Petitioner's left shoulder symptomology began within forty-eight hours of her June 30, 2020 vaccination, is her own words as outlined in her [a]ffidavit." Respondent's Response at 13 (citing Petitioner's Motion at 2; Ex. 1). And, Respondent notes, the Court may not rule for Petitioner solely based on her sworn claims. *Id.*

Additionally, Respondent contends that, contrary to Petitioner's assertions, the contemporaneous medical records from ten days post vaccination "are devoid of any discussion about shoulder or arm pain." Respondent's Response at 13-14 (citing Ex. 5 at 17-19; Ex. 1 ¶ 8). Respondent argues that if Petitioner had a hot, swollen shoulder and difficulty moving her arm and told the urgent care physician about such symptoms as alleged in her affidavit at this time, "it is reasonable to expect that the provider would have documented those concerns and observations[,]" but they do not. *Id.* at 14. More so, Respondent argues that when the records document "left arm" pain beginning post vaccination (on July 15, 2020), there are no specifics about how soon after the vaccination Petitioner's pain began. *Id.*

While Respondent's assertions are accurate, the totality of the medical record supports the conclusion (if barely) that Petitioner's shoulder pain most likely began within 48 hours of receiving her June 30, 2020 Tdap vaccination. For instance, Petitioner first attributed her *shoulder* pain to the subject Tdap vaccination three months post vaccination, on September 30, 2020.[5] Ex. 4 at 79. She provided additional context at that time and explained that she "woke up from the pain the night after she got her immunization [and s]he had pain for two days after the injection." *Id.* Additionally, on February 1, 2022, (albeit after the claim's initiation), Petitioner reported that she experienced left shoulder pain "immediately since [her] tetanus shot." Ex. 11 at 21. While this later statement was indeed made after Petitioner began pursuing her claim, it is corroborated by the September 30, 2020 statement made closer in time to Petitioner's subject Tdap vaccination and I therefore will give such statements appropriate weight. Further, while not a contemporaneous medical record, the VAERS report authored on March 12, 2021, notes onset on June 30, 2020 – the day of Petitioner's Tdap vaccination. Ex. 3. Such records, taken together, thus provide support for onset within 48 hours of the subject vaccination.

I must note, however, that this is a case where certain intervening records indeed rebut Petitioner's contentions that her shoulder pain began immediately post vaccination. Despite Petitioner's assertions made in her affidavit (that pain, swelling, redness, and heat at the injection site occurred on the day of vaccination and that she reported this to the urgent care facility the day following the subject Tdap vaccination and ten days later, on July 10, 2020), the medical records do not fully corroborate such assertions. *Compare* Ex. 1 ¶¶ 7-8, *with* Ex. 5 at 17-20, 24. It is somewhat reasonable that these records do not contain mention of Petitioner's alleged left shoulder pain, since they reflect medical visits for other issues. Still, I cannot credit Petitioner's assertions on this point without contemporaneous support in the medical record. And, when Petitioner presented to *her PCP* (with whom she eventually sought care for her shoulder injury) in July and August 2020 and still did not mention vaccine-related *left shoulder* pain specifically (but rather general aches and pains, "arm pain," neck pain, and back pain), these omissions call into question whether Petitioner's left shoulder pain around that time was as severe as she alleged in her affidavit. *Compare* Ex. 4 at 89-110, *with* Ex. 1 ¶¶ 7-8.

I will also note that Petitioner's medical records contain consistent reports of Petitioner's left shoulder pain beginning after her Tdap vaccination. *See,* e.g., Ex. 4 at 34, (a March 16, 2021 PCP note showing "ongoing . . . pain of the left arm [that] started after

[5] Petitioner's medical records show that she first questioned the Tdap vaccination's association with her symptoms on July 15, 2020, but she questioned the association between the vaccination and her "neck discomfort and mid-back pain" not her shoulder pain at that time. Ex. 4 at 107. On July 27, 2020, Petitioner questioned a reaction to her Tdap vaccination based on her "arm pain [and] generalized muscle aches and pains," not her left shoulder, specifically. *Id.* at 102.

a Tdap injection [in] June of last year"); Ex. 4 at 441 (a March 23, 2021 note stating Petitioner "got a tetanus shot last June and her pain has not resolved"); Ex. 8 at 2 (a March 4, 2021 note attributing left shoulder pain to a tetanus shot "9 mo[nths] ago"). While such notations do not describe onset occurring within 48 hours of vaccination, they still may provide support for Petitioner's ability to satisfy any causation-in-fact claim for her alleged left shoulder injury.

Thus, balancing all of the above, the evidence *barely* supports the conclusion that the onset of Petitioner's left shoulder pain began within 48 hours of her June 30, 2020 vaccination. Petitioner has satisfied the second QAI criterion.

**3. Scope of Pain and Limited Range of Motion**

The third QAI requirement for a Table SIRVA requires a petitioner's pain and reduced range of motion to be "limited to the shoulder in which the intramuscular vaccine was administered." 42 C.F.R. § 100.3(c)(10)(iii).

Respondent contests that Petitioner's pain was limited to her left shoulder. Respondent's Response at 11. Petitioner complained of "generalized muscle aches and pains" and "systemic symptoms" post vaccination, along with neck discomfort and mid-back pain, followed by a "vague reference to 'arm pain,'" generally. *Id.* at 12 (citing Ex. 4 at 102, 105, 107). In addition, Petitioner's post-vaccination treatment mainly pertained to the *opposite* arm and shoulder – and presented the same way in both arms. *Id.*

The record is largely consistent with Respondent's contention that Petitioner's pain was not limited to her left shoulder. Indeed, soon after vaccination, by July 15, 2020, Petitioner complained of a "question of a reaction to a tetanus vaccination *including neck discomfort [and] mid back pain*." Ex. 4 at 110 (emphasis added). Later that month, on July 27, 2020, Petitioner reiterated her concern regarding a vaccine reaction presenting with "arm pain [and] generalized muscle aches and pains." *Id.* at 102. Petitioner was prescribed a steroid to treat the "systemic symptoms" of the potential adverse reaction. *See id.* at 105. She even reported improvement of "her aches and pains" following this course of steroids. *Id.* at 98-101. Ultimately, Petitioner was primarily treated for pain in the *opposite* shoulder than the one in which the subject Tdap vaccination was administered (to be discussed in more detail below). *See,* e.g., Ex. 4 at 42, 48, 68-73, 77-82; Ex. 8 at 2.

In the Program, special masters have found that claims involving musculoskeletal pain *primarily* occurring in the shoulder are valid under the Table even if there are additional allegations of pain extending to adjacent parts of the body. *K.P. v. Sec'y of*

*Health & Hum. Servs*., No. 19-65V, 2022 WL 3226776, at *8 (Fed. Cl. Spec. Mstr. May 25, 2022) (holding that "claims involving musculoskeletal pain primarily occurring in the shoulder are valid under the Table even if there are additional allegations of pain extending to adjacent parts of the body").

However, the gravamen of the third QAI criterion is intended to "guard against compensating claims involving patterns of pain or reduced [ROM] indicative of a contributing etiology beyond the confines of a musculoskeletal injury to the affected shoulder." *Grossmann v. Sec'y of Health & Hum. Servs.,* No. 18-0013V, 2022 WL 779666, at *15 (Fed. Cl. Spec. Mstr. Feb. 15, 2022). Thus, special masters balance complaints about shoulder pain, and associated treatment, against evidence that the overall presentation is more systemic. *See,* e.g., *Cross v. Sec'y of Health & Hum. Servs*., No. 19-1958V, 2023 WL 120783, at *7 (Fed. Cl. Spec. Mstr. Jan. 6, 2023) (finding that "despite the notations of pain extending beyond the shoulder, Petitioner's injury is consistent with the definition of SIRVA and there is not preponderant evidence of another etiology"); *Werning v. Sec'y of Health & Hum. Servs.*, No. 18-0267V, 2020 WL 5051154, at *10 (Fed. Cl. Spec. Mstr. July 27, 2020) (finding that a petitioner satisfied the third SIRVA QAI criterion where there was a complaint of radiating pain, but the petitioner was "diagnosed and treated solely for pain and limited range of motion to her right shoulder").

Here, this is not a case where Petitioner had "stray notations" of pain extending beyond the shoulder but whose injury was still consistent with SIRVA. *See K.P.,* 2022 WL 3226776, at *8. Rather, here there is evidence that Petitioner initially complained of, and was successfully treated, for generalized and "systemic" symptoms of muscle "aches and pains" – not specific to or focused on the left shoulder nor radiating from the shoulder. *See* Ex. 4 at 98, 102, 105. Overall, the medical records do not consistently reflect a new injury localized to the left shoulder as the *primary* complaint, that can be isolated from other incidental complaints of pain elsewhere. Petitioner has therefore failed to establish this QAI criterion.

**4. Other Condition or Abnormality**

The last QAI criteria for a Table SIRVA states that there must be no other condition or abnormality which would explain a petitioner's current symptoms. 42 C.F.R. § 100.3(c)(10)(iv). For several reasons very similar and closely related to the issues discussed with respect to the third criterion, this criterion is also not met given the facts of this case.

The records show that Petitioner suffers from severe, end-stage degenerative joint disease/primary glenohumeral OA of *both* shoulders. *See* Ex. 4 at 443; Ex. 8 at 2; Ex. 11

at 7, 17-21, 23-24, 63. While the dates of diagnosis in each shoulder differs (diagnosed in the right shoulder in March 2021 and diagnosed in the left shoulder in February 2022), the same diagnosis is present bilaterally. *See,* e.g., Ex. 4 at 443; Ex. 11 at 17. In fact, Petitioner's symptomology, imaging, and course of treatment in her right, non-SIRVA shoulder is largely the same as the left – just sooner in time.

For instance, Petitioner complained of left shoulder pain on September 24, 2020, and as a result received a steroid injection in the left shoulder. Ex. 4 at 84. Less than one week later, by September 30, 2020, Petitioner complained of *right* shoulder pain and her focus, almost exclusively, became her right shoulder thereafter. *Id.* at 82. She was subsequently treated with three steroid injections in the right shoulder. *See id.* at 48, 73, 82. When the steroid injections proved unsuccessful, Petitioner ultimately underwent an x-ray of the right shoulder in March 2021, which revealed "bone on bone at [the] glenohumeral joint" and confirmed her OA diagnosis in that shoulder. *Id.* at 443. Petitioner then had a right shoulder arthroplasty (replacement) in August 2021. Ex. 11 at 63. Similarly, when Petitioner's left shoulder pain persisted, she underwent x-rays and an MRI that showed "near bone on bone at [the] glenohumeral [joint]" in April 2021, but later progressed to "end stage," "bone on bone" degenerative joint disease by February 2022. Ex. 10 at 5-7; Ex. 11 at 17-24. A left shoulder arthroplasty was suggested. Ex. 11 at 17.

While evidence of a concurrent condition or abnormality does not *per se* preclude a Table SIRVA claim (or the ability to establish the fourth QAI criterion), there is simply too much overlap between Petitioner's *bilateral* shoulder symptoms, treatment, imaging, and diagnoses to rule out Petitioner's OA as explanatory of her alleged post-vaccination left shoulder symptoms. *See Lang v. Sec'y of Health & Hum. Servs.,* No. 17-995V, 2020 WL 7873272, at *12-13 (Fed. Cl. Spec. Mstr. Dec. 11, 2020) (emphasizing that "findings consistent with impingement, rotator cuff tears, or [acromioclavicular] arthritis do not *per se* preclude a finding that a Table SIRVA exists," rather the question is whether the petitioner's "shoulder pathology wholly explain[ed] her symptoms independent of vaccination."). The record as a whole supports that there is another abnormality that could explain Petitioner's post-vaccination left shoulder complaints other than the subject Tdap vaccination.

## Conclusion

At bottom, it is the overall mix of evidence herein that causes me to find Petitioner's Table claim cannot be preponderantly established. Petitioner has not provided preponderant evidence that her pain and limited ROM was localized to the shoulder in which the vaccine was administered, and there is another condition or abnormality present that could explain Petitioner's post-vaccination symptoms. Nevertheless, a non-

Table claim *could* be viable, and I therefore do not dismiss the case in its entirety at this time. I urge the parties to make one final brief attempt at settlement, since the case will likely be transferred out of SPU shortly so that Petitioner can attempt to establish a causation-in-fact claim – likely requiring the retention of experts.

Accordingly, Petitioner's Table SIRVA claim is **DISMISSED.** Petitioner shall file a joint status report indicating that she has provided Respondent with a revised settlement demand for her off-Table claim (and one that takes into account litigative risk in attempting to prove a non-Table SIRVA that was not localized to the shoulder and could be explained by another condition), and the parties' efforts towards informal resolution, **by no later than Friday, March 22, 2024.** If the parties do not report progress in their efforts, the matter will be transferred out of SPU.

**IT IS SO ORDERED.**

**s/Brian H. Corcoran**
Brian H. Corcoran
Chief Special Master